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| 10/501,670 | 01/18/2005 | Hideji Tajima | 10287.65 | 2325 |
| 27683 7590 04/29/2009 HAYNES AND BOONE, LLP IP Section 2323 Victory Avenue Suite 700 Dallas, TX 75219 | | | | |
| EXAMINER | | | | |
| POPA, ILEANA | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,670

Applicant(s)

TAJIMA, HIDEJI

Examiner

ILEANA POPA

Art Unit

1633

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-14 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-14 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/06/2009 has been entered.

Claims 2, 3, and 15 have been cancelled. Claims 1, 5-10, 12-14, 17, and 18 have been amended.

Claims 1, 4-14, and 16-20 are pending and under examination.

2. All rejections pertaining to claims 3 and 15 are moot because Applicant cancelled the claims in the reply filed on 02/06/2009.

The rejection of claims 1, 4-14, and 16-18 under 35 U.S.C. 103(a) as being unpatentable over Safir et al. (U.S. Patent No. 6,491,823), in view of each Tajima et al. (U.S. Patent No. 5,702,950), Ikeda et al. (U.S. patent No. 6,607,662), and Deschamps et al. (Protein Expression and Purification, 1995, 6: 555-568 is withdrawn in response to Applicant's amendments to the claims filed on 02/06/2009.

Maintained rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4-9, 12-14, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tajima (U.S. Patent No. 5,895,631, of record).

Tajima teaches a pipette device for separating high molecular substances of interest, the device comprising a drawing/discharging section having a nozzle which connects to a detachable cylinder chip having an inlet/outlet, wherein the cylinder chip is loaded with magnetic particles coupled to biotin or streptavidin (i.e., a carrier housing), wherein the drawing/discharging section draws fluid into the cylinder chip via the inlet/outlet and discharges the fluid out of the cylinder chip via the same inlet/outlet; the magnetic particles are held in a predetermined position due to a magnetic field and the cylinder chip comprises a small diameter section in contact with the fluid to be drawn, an intermediate diameter section which captures the magnetic particles, and a large diameter section (i.e., opening) detachably connected to the nozzle (claims 1, 2, 12, 14, 19, and 20) (column 3, lines 50-67, column 4, lines 22-30 and 59-67, column 5, lines 14-22, column 6, lines 17-67, column 7, lines 7-27, 65, and 67, column 8, lines 1-7, Fig. 7, claims 1, 3-5, and 9). Tajima teaches that the pipette device has a transferring section capable of transferring the carrier housing with respect to outside containers comprising different reagents (claims 1, 15, and 16) (column 7, lines 37-48, column 8, lines 8-67). Tajima also teaches that the detachable chips can further contain filter tips, wherein the

filter tips can contain silica filters (i.e., porous glass) (claims 5, 8, and 13) (column 4, lines 22-37, column 9, lines 33-40, column 13, lines 54-58, Fig. 7 and 13). Tajima et al. do not teach their magnetic particles having a size such that they are not capable to pass through the inlet/outlet (claims 1, 4, 9, 14, 17), nor do they teach their large diameter section as comprising a filter (claims 19 and 20). However, one of skill in the art would know to provide the large diameter section with a filter; one of skill in the art would be motivated to so in order to avoid contaminating the pipette nozzle. With respect to the magnetic particles not being able to pass through the inlet-outlet, one of skill in the art would be motivated to do such in order to avoid loss of magnetic beads (and therefore, loss of captured material). It is noted that by doing such, one of skill in the art would necessarily remove the carrier through the large diameter section (claim 18). With respect to the limitations recited in claims 6, 7, and 9 one of skill in the art would have known to use the claimed adhesion prevention and holding sections when needed. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Applicant argues that, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, Applicant argues, Tajima does not disclose the subject matter of amended claim 1, as recited above, specifically a carrier formed in a size or a shape not allowing said carrier to pass through said inlet/outlet. This lack of disclosure was confirmed by the Examiner, who nevertheless asserted that this limitation is obvious in view of Tajima. Applicant points out that, in response to the

final Office Action mailed August 7, 2008, he argued that the Examiner's proposed modification of Tajima renders Tajima unsatisfactory for its intended purpose. Applicant agrees with the Examiner's statement that the intended purpose in Tajima is to separate the magnetic particles from the rest of the reaction fluid (Advisory Action mailed November 26, 200). However, Applicant argues that the Examiner's suggested modification of particles already within the cylindrical chip and having a size not enabling them to pass through the inlet-outlet outside of the cylindrical chip renders Tajima wholly unsatisfactory for its intended purpose. Applicant argues that, in order to be satisfactory for its intended purpose, namely separating the magnetic particles from the rest of the reaction fluid, Tajima requires that the magnetic particles be able to pass through the inlet/outlet (column 17, line 36 through column 18, line 2). The Examiner's suggested "modification" of Tajima, which requires that the magnetic particles not be able to pass through the inlet/outlet, clearly renders Tajima unsatisfactory for its intended purpose. Applicant argues that, since a modification cannot render a reference unsatisfactory for its intended purpose (MPEP 2143.01 V) the rejection of amended claim 1 under 35 U.S.C. §103(a) over Tajima is inapplicable. Applicant argues also that the suggested modification which proposes that the magnetic particles are already within the cylinder chip and thus are already separated from the reaction fluid, renders the teaching of Tajima useless or irrelevant, much less unsatisfactory for its intended purpose, because there is no longer a need to employ the teaching of Tajima to separate the magnetic particles from the rest of the reaction fluid. Applicant argues that claims 4, 5, 8, 12, 13 and 19 (which depend from claim 1), claim 14 (which

is a method version of claim 1), and claims 16-18 and 20, (which depend from claim 14) are allowable for at least the same reasons as noted above with respect to claim 1.

Therefore, Applicant requests the withdrawal of the rejection.

Applicant's arguments are acknowledged, however, they are not found persuasive for the following reasons:

The argument that the proposed modification renders Tajima wholly unsatisfactory for its intended purpose is not new and has been answered in the Advisory Action mailed on 11/26/2008. Applicant argues that Tajima requires that the magnetic particles be able to pass through the inlet/outlet. However, the passage indicated by Applicant to support his argument (i.e., column 17, line 36 through column 18, line 2) only discloses that separating the magnetic particles from the fluid is achieved by pulling in the magnetic particles together with the reaction fluid, retaining the magnetic particles via applying a magnetic field, and discharging the reaction fluid. Tajima does not teach that passing the magnetic particles through the inlet/outlet is necessary for separating them from the reaction fluid. In fact, Tajima teaches that passing the magnetic particles through the inlet/outlet results in the magnetic particles being mixed with the fluid and not separated from the fluid. As noted in the Advisory action, and as Applicant admits, the principle of operation is separating the magnetic particles from the reaction fluid and not discharging the magnetic particles in the fluid (i.e., mixing the magnetic particles with the fluid). As long as this separation occurs, the principle of operation is not changed. The proposed modification achieves such

separation and therefore, Applicant's arguments are not found persuasive. For these reasons, the rejection is maintained.

New Rejections/objections

Claim Objections

4. Claim 1 is objected to because of the following informalities: the recitation of "smaller diameter" in line 7 is redundant, since the claim already recites "a small diameter section connected to the large diameter section", i.e., it is clear that the diameter is smaller. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4-14, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tajima (U.S. Patent No. 5,895,631, of record), in view of both Tajima (U.S. Patent No. 5,919,706) and Tajima (U.S. Patent No. 6,100,079).

The teachings of Tajima '631 are applied as above for claims 1, 4-9, 12-14, and 16-20. Although Tajima '631 teaches their device as useful for separating high molecular substances of interest, he does not specifically teach monitoring separation by using a translucent chip (i.e., a translucent carrier housing) and an outside apparatus

for measuring luminescence on the carrier (claim 10). However, doing such is suggested by the prior art. Tajima '079 teaches that pipette devices such as the ones disclosed by Tajima '631 can be used to monitor the binding of high molecular substances of interest to magnetic beads, wherein monitoring takes place via luminescence (column 5, lines 40-54; column 7, lines 53-65). Although Tajima '079 does not specifically disclose translucent chips and an outside measuring apparatus, using such is taught by the prior art (see Tajima '706, column 3, lines 44-50; column 7, lines 34-45). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the device of Tajima '631, according to the teachings of Tajima '079 and Tajima '706, to achieve the predictable result of monitoring the separation of the macromolecule of interest. With respect to the limitation of the carrier housing having a side face made in a plane (claim 11), one of skill in the art would know to modify the chip (i.e., the carrier housing) according to the measuring equipment used. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

7. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/
Examiner, Art Unit 1633